STANDARD Table

T-MH01: Medical History by SOC and PT

VERSION 3.0

| TABLE 14.1\_\_x.x  Medical History by System Organ Class and Preferred Term  (Analysis Population) | | | | | |
| --- | --- | --- | --- | --- | --- |
|  | | -------------- Test Treatment ---------------- | | |  |
| MedDRA xx.x System Organ Class  Preferred Term | Control  (N=x)  n (%) | Arm 1  (N=x)  n (%) | Arm 2  (N=x)  n (%) | Total  (N=x)  n (%) | Total  (N=x)  n (%) |
|  |  |  |  |  |  |
| System Organ Class 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Preferred Term 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Preferred Term 2 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Preferred Term ... | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |  |
| System Organ Class 2 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Preferred Term 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Preferred Term 2 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Preferred Term ... | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |  |
| System Organ Class ... | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Preferred Term 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Preferred Term 2 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Preferred Term ... | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |  |
| Note: Subjects are counted once in each category regardless of the number of events they have had. | | | | | |

# Study-Specific Text (to be supplied by Statistician unless otherwise noted)

Analysis Population

Full Analysis Set

Intent to Treat Population

Safety Analysis Set

Safety Population

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Treatment Groups

Control \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Control … \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Test Treatment Arm 1 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Test Treatment Arm 2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Test Treatment Arm … \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

MedDRA Version: Obtain from data

System Organ Class and Preferred Term: Obtain from data

# Optional Columns and Rows

All Total (T1)

Test Treatment Total (T2)

# Version History

|  |  |  |
| --- | --- | --- |
| **Version** | **Description** | **Effective Date** |
| 1.0 | Initial version describing how to add functionality to standard TLF shells. |  |
| 2.0 | Updated Analysis Population options for consistency across all tables.  Updated Test Drug to Test Treatment as referenced in eCRF standard. |  |
| 3.0 | Changed the title to one line.  Changed “Active Total” to “Test Treatment Total”.  Changed “in each row” to “in each category” in the footnote. |  |